REMARKS

Claims 1, 3-7, 9, 17, 18, and 21 have been amended herein. Claims 8 and 10-13 were cancelled in previous Responses. Claims 1-7, 9, and 14-24 are presented for the Examiner's review and consideration. Applicants believe that the claim amendments and accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Notice of References Cited (PTO-892 form)

Applicants note that the Examiner cited a patent, U.S. Patent 5,423,736, issued to Cartmell et al., on the PTO-892 form attached to the current final Office Action. However, this patent is not referenced in the Office Action. Thus, Applicants respectfully request clarification as to whether or not the Examiner meant to rely upon this patent in support of the rejection(s).

Amendments to the Specification

No new matter has been added by the amendments to paragraph **[0027]** of the published application (U.S. Patent Application Publication 2006/0142708 A1; hereinafter "published application") made herein. This paragraph was amended only to correct inadvertent errors in grammar and punctuation.

Applicants note that the title of the application as filed is "A Method for Removing Pigments From A Pigmented Section of Skin" however, the title was printed in the published

application as "Method for Removing Pigments From A Pigmented Section of Skin." Accordingly, Applicants respectfully request correction.

Amendments to the Claims

No new matter has been added by the amendments to claims 1, 3-7, 9, 17, 18, and 21 made herein. These claims were amended to provide consistency of language, to provide proper antecedent basis for all terms recited, and to correct inadvertent typographical errors, including correction of errors in grammar and punctuation.

Rejections under 35 U.S.C. §103(a)

Claims 1-6, 9, 14-18, and 21-24 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Malodobry (U.S. Patent Application Publication 2004/0111107 A1; hereinafter "Malodobry") in view of Auguste et al. (U.S. Patent 6,375,977 B1; hereinafter "Auguste"). Claims 7, 19, and 20 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Malodobry in view of Auguste et al. and further in view of Garitano et al. (U.S. Patent Application Publication 2004/0158196 A1; hereinafter "Garitano"). For reasons set forth below, Applicants respectfully submit that both of these rejections should be withdrawn.

It is noted that the references are described separately only to clarify what each reference teaches and not to argue the references separately.

Malodobry

Malodobry discloses a method for scarless removal of tattoos from human or animal skin. *See* abstract and paragraph **[0039]**. The method includes passing one or more tools (needles), which have rough or sharp-edged surfaces, through a pigmented skin surface in a manner essentially perpendicular thereto. *See* abstract and paragraphs **[0042]** and **[0045]**. The needles

enter agglomerates of color pigments and mechanically destroy them by breaking up the fragments. *See* abstract and paragraphs **[0041]-[0045]**. The smaller fragments of the agglomerates are eliminated by the natural healing process of the skin and the vitality of the cells is preserved. *See* paragraphs **[0041]**; **[0048]**; and **[0049]**. The method may also include application of skin irritants to skin surface and/or introduction of the skin irritants into the agglomerates before, during, or after the mechanical destruction. *See* paragraph **[0050]**. The skin irritants encourage inflammation and/or provide fillers in the cells to delay wound healing and thus, allow for maximum fragment elimination. These irritants can be solid or liquid and may include table salt. *See* paragraphs **[0051]** and **[0052]** and claim 1.

Auguste

Auguste discloses a hydrocolloid adhesive mass, which is useful for medical purposes such as dressing wounds, exhibiting increased absorption during the first few hours of use. *See* abstract and column 1, lines 8-16. This mass includes an ethoxylated sorbitan fatty acid ester incorporated into a conventional hydrocolloid adhesive mass. *See* abstract and column 2, lines 50-55. This composition gives the mass high absorption without impairment of its physical properties of cohesion, adhesion, integrity, elasticity, and long-term manageability. *See* column 2, lines 42-47 and column 17, lines 20-27. The addition of an ethoxylated soribitan fatty acid ester to a hydrocolloid adhesive mass, affords a significant increase in the capability of the mass to discharge absorbed fluids by increasing the permeability to water vapor. These masses are then used to produce dressings which are capable of both eliminating the absorbed fluids, and maintaining an absorption-elimination equilibrium and a moist environment favorable to healing. *See* column 2, lines 56-67.

Garitano

Garitano discloses a device (and methods for using the device) for needleless administration of permanent makeup and tattoos. *See* abstract and paragraph **[0006]**. In particular, the device relates to hypodermic injectors for use in delivering pigment or other

substances to targeted layers of the skin. With use of this device, one is able to avoid needlestick injuries and reduce transmission of disease. *See* abstract and paragraph **[0016]**. Material is delivered by accelerating compressed air and can be dispersed throughout a greater volume of tissue as compared to dispersion with a conventional needle. *See* paragraphs **[0016]**; **[0033]** and **[0034]**. Garitano also contemplates removal of pigment using the described device, including methods involving injection of a removal solution and suction or drainage of the solution from the skin. *See* paragraph **[0023]**.

Instant Invention

The instant invention, as currently claimed, is a method for the removal of pigments from a pigmented section of skin, such as a tattoo. *See* abstract and paragraphs **[0001]** and **[0014]** of the published application. The method involves puncturing the skin in the pigmented area with at least one needle or other skin-puncturing device to liberate the pigments and cellular fluids from cells containing the pigments. The punctured skin is then bandaged using a pad adapted to absorb the pigments and cellular fluids. Prior to bandaging, the pad is treated with a material, such as a salt-based granular paste, that accelerates the migration of pigments toward the outer layer of skin, where they are quickly absorbed by the pad. *See* abstract and paragraphs **[0014]** and **[0027]-[0032]** of the published application. The pad is preferably removed prior to complete saturation and/or before the material in the pad causes skin damage. *See* paragraph **[0029]** of the published application. The method can also include application of antiseptic and/or antibiotics to the punctured skin. *See* paragraphs **[0016]** and **[0031]** of the published application. Additionally, the skin-puncturing device can include a suction means for suction of the pigments during puncturing of the skin. *See* paragraphs **[0019]** and **[0033]** of the published application.

Argument

Applicants respectfully submit that the combination of Malodobry and Auguste does not obviate the invention as currently claimed. Claim 1 recites, *inter alia*, a method for removing

pigments from a pigmented section of skin, for example, from a tattoo. This method includes, *inter alia*, two steps: first puncturing the pigmented area of skin with a skin-puncturing device to release the pigments and cellular fluids from the pigment-containing cells and then bandaging the punctured skin with a pad to absorb the pigments and cellular fluids. The pad used for the absorption contains a salt-based granular paste which acts to accelerate migration of the pigments toward the outer layer of skin such that they are quickly absorbed.

The Examiner concludes that the claimed invention can obviously be obtained by using the pad disclosed by Auguste in the method disclosed by Malodobry. Applicants respectfully disagree. Neither the pad of Auguste nor the method of Malodobry is akin to that of the claimed invention.

First, Applicants turn to the pads. The pad used in the claimed method is distinct from the pad described by Auguste in both composition and function. In order to understand the differences, one must first understand the purpose for which each of these pads was developed. Auguste is attempting to provide a dressing whose role is "*to absorb these fluids* (*i.e.* the fluid exuded from deep wounds or burns) *while at the same time maintaining in contact with the wound a moist environment which favors the healing process*." *See* column 1, lines 37-39. In order to accomplish this goal, Auguste designed his dressing taking into consideration the following points:

a. In the first few hours of the healing process large amounts of fluid are exuded from a wound. As time passes and the wound begins to heal the amount of fluid that has to be absorbed by a dressing decreases.

b. It is detrimental to the healing process to remove the dressing frequently; therefore the dressing must be capable of remaining in place for a period of two to four days (column 1, lines 52-53). During this entire period the dressing must be capable of absorbing large quantities of fluid, especially at the beginning of the period, without on the one hand, becoming over saturated such that the dressing "leaks" fluid out onto the patient, his clothing, and/or bedding, etc. and, on the other hand, must retain enough of the exuded fluid to maintain a moist environment at the surface of the wound.

c. The dressing must not contain material that would cause any irritation or injury to skin since it is to be left in place for a few days.

In contrast, the pad used in the claimed method was developed to quickly absorb pigments/cellular fluids and to remain in place for only a short period of time. This method is a method of eradicating tattoos by repeatedly pricking the skin in the area of the tattoo in order to destroy cells and release the pigments enclosed within them. Since the pores made by the needles close in a manner of minutes, trapping the released pigments inside the upper layers of skin, the instant inventors searched for a way to increase the rate at which pigment fragments that were released from the cells migrated to the surface in order to successfully remove the tattoo with a single treatment during the narrow "window of opportunity" estimated to be 40-60 minutes. Therefore, the pad needed to accomplish this goal had to have the following properties:

a. The pad must be able to actively accelerate the process of migration of essentially all of the pigments and cellular fluid released from the cells that were mechanically destroyed by the needles toward the outer layer of skin.

b. The pad must be able to accomplish this task in a manner of minutes before the natural healing process of the skin results in the closing of the pores made by the needles.

Furthermore, Auguste and the instant inventors solved their respective problems with "dressing development" in different ways.

Auguste invented a dressing made by adding an ethoxylated sorbitan fatty acid ester to a traditional hydrocolloid adhesive mass. According to Auguste, the addition of the ester significantly increases the permeability of the hydrocolloid mass to water vapor. Thus, this hydrocolloid mass could be used to produce dressings that satisfy the requirements described above. The dressing could absorb and retain moisture. Further, when in use, excess water was easily and rapidly expelled from the dressing into the surroundings, thus preventing over-saturation, especially in the critical first few hours of use when relatively large amounts of fluid have to be absorbed. The dressing contains no material that would be harmful to skin and is left

in place for a lengthy period of time (disclosed as 2-4 days).

The instant inventors solved their problem by adding one or more materials to an ordinary cotton mesh gauze pad. The material added is preferably an inorganic, salt-based granular paste. This salt-based granular paste acts to accelerate migration of the released pigments and fluids toward the outer layer of skin where they are quickly absorbed into the cotton gauze. The paste contains a very high concentration of salt, which would cause irritation and potentially serious damage to the skin if the pad was left in place for more than a few minutes.

The table below summarizes the differences between the dressing disclosed by Auguste and the pad used in the claimed method.

Property	**Auguste**	**Present Invention**
method of acting	passively absorbs fluids exuded from wounds	actively draws pigments and cellular fluids toward the outer layer of skin
material	ethoxylated sorbitan fatty acid ester added to a traditional hydrocolloid adhesive mass	inorganic salt-based granular paste added to a cotton mesh gauze pad
duration of contact with the skin	2-4 days	several minutes
contains irritating or harmful material	no	yes

Therefore, based upon all of the above, it is clear that the pad used in the claimed method is not equivalent to the dressing of Auguste, either in structure (composition), function, or method of use.

Applicants now turn to the methods. As repeatedly discussed in previous Responses, the method of Malodobry is <u>not</u> akin to the method of the claimed invention, and further, is in fact opposite therefrom, as it teaches preserving rather than destroying the pigment-containing cells.

The method taught by Malodobry appears to be superficially similar to that of the claimed invention since both are based on use of a machine similar/identical to a tattooing machine to penetrate the skin with one or more needles into the dermis where the tattoo pigments reside. However, the two methods actually differ in at least the following significant ways:

In an attempt to distinguish his invention from that of diathermy, Malodobry states that, "*...in the treatment according to the invention, no liquid cell substance is evaporated. The vitality of the cell is to be preserved, if possible*." See paragraph **[0048]**. Thus, it is clear that Malodobry teaches making every effort to avoid damage to the cells in the dermis. This is in stark contrast to the method of the claimed invention in which the object of penetrating the skin is to destroy as many of the pigment-containing cells as possible and absorb the pigments and the liquid cell substance released.

Malodobry relies on natural processes to cause the fragments to be carried to the skin surface as stated, for example in paragraph **[0049]**. "*The usual wound healing conveys the color pigment agglomerate fragments to the skin surface where they are then scaled off*." This a passive approach compared to the active approach of the method of the claimed invention, which requires use of a pad including a salt-based granular paste which causes the released pigments to migrate into the outer layer of the skin. Actively drawing the pigments and cell fragments to the surface accelerates the process and also reduces the number of particles that remain behind and are re-trapped in the dermis. Thus, it is possible to remove an entire tattoo in one treatment.

Based on all of the above, it is clear that Malodobry teaches a method that is quite different from that of the invention.

Additionally, Applicants respectfully submit that many of the Examiner's assumptions regarding the teachings of the cited references are misguided at best.

With regard to Auguste, the Examiner asserts that "*the pad contains one or more materials adapted to accelerate the rate of absorption (or migration) within the first few hours in order to minimize the inflammatory process of healing (col. 2, lines 1-15).*"

Applicants respectfully disagree. At column 2, lines 1-15, Auguste describes one of the problems that he is trying to solve with his invention, *i.e.* maintaining hemostatic equilibrium of the wound. The solution that he proposes is presented in column 2, lines 50-55, which is to add an ethoxylated sorbitan fatty acid ester to a traditional hydrocolloid adhesive mass. The addition of the ester does not accelerate the rate of absorption but rather *"affords a significant increase in the capacity of said mass to discharge the absorbed fluids by increasing the permeability to water vapor." See* column 2, lines 60-62. Auguste neither teaches nor suggests addition of any material to increase the rate of absorption. Therefore, in contrast to the Examiner's assertion, Auguste does not teach addition of a material to increase the rate of absorption of fluid, but rather addition of a material that increases the rate at which the dressing can rid itself of excess fluid and maintain equilibrium.

Again with regard to Auguste, the Examiner asserts that *"the material can be paste-like (col. 4, lines 25-36 and elsewhere) and contain salts including saline (col.6, line 54)."*

Applicants respectfully disagree. At column 4, lines 25-36, Auguste is describing the adhesive matrices which are used in the production of the hydrocolloid and not any material that it is added to the dressing prior to use. There is no mention of any "paste-like" material in column 4 or elsewhere. At column 6, lines 52-54, in contrast to the Examiner's assertion, Auguste does not refer to saline, but rather to organic polymer salts, *i.e.* alkali metal salts of cellulose derivatives. These organic polymer salts do not have the same chemical or physical properties of inorganic salts and cannot be used to replace the granular paste used in the claimed method.

Additionally, the Examiner asserts *"Obviously the pad will eventually be removed at some point. It should be removed before damage occurs and/or to avoid patient discomfort which may arise from the use of the chemicals disclosed by Auguste et al. Also, the pad should be removed before saturation so that it can absorb more fluid... The use of a pad capable of*

absorbing the claimed amount of debris is considered obvious to a person having ordinary skill in the art."

Applicants respectfully submit that these statements are unsubstantiated and irrelevant to what the references cited and the claimed invention teach. Auguste makes no mention of any chemicals or materials which may cause damage and/or patient discomfort and would not be expected to as the dressing is in contact with the skin for days. Further, the dressing disclosed by Auguste is designed to eliminate excess fluid and can stay in place for 2-4 days. The increased acceleration of the rate of migration of released pigments/cellular fluid provided by the pad used (in the claimed method), is the relevant property and not absorption of any "claimed amount of debris."

Independent claim 1 recites, *inter alia*, a method for removing pigments from a pigmented section of skin, including two general steps: first puncturing the pigmented area of skin with a skin-puncturing device to release the pigments and cellular fluids from the pigment-containing cells and then bandaging the punctured skin with a pad to absorb the pigments and cellular fluids. The pad used for the absorption contains a salt-based granular paste which acts to accelerate migration of the pigments toward the outer layer of skin such that they are quickly absorbed.

As established by all of the above arguments, neither the cited patent/patent application nor any other prior art describes such a pad that increases acceleration of the migration of pigments and enables removal of a tattoo in one treatment. One of ordinary skill in the art would have no reason or motivation to combine the teachings of Malodobry and Auguste as they would not consider the methods and pads disclosed as at all similar or related to the claimed method or effective for the same purposes.

Accordingly, Applicants respectfully submit that claims 1-6, 9, 14-18, and 21-24 are patentable over Malodobry in view of Auguste. As claims 2-6, 9, 14-18, and 21-24 depend from claim 1, these dependent claims necessarily include all of the elements of their base claim. Thus, Applicants respectfully submit that the dependent claims are allowable over Malodobry in view of Auguste for at least the same reasons.

Regarding the rejection of claims 7, 19, and 20, also dependent upon claim 1, the disclosure of Garitano does not remedy the deficiencies of Malodobry and Auguste, as described above, since Garitano does not teach or suggest addition of any material to a dressing or pad to increase acceleration of the migration of released pigments/cellular fluid as in the claimed method. Accordingly, Applicants respectfully submit that claims 7, 19, and 20 are patentable over Malodobry in view of Auguste et al. and further in view of Garitano, at least for the reasons stated above.

In light of all of the foregoing arguments, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-7, 9, and 14-24 under 35 U.S.C. § 103(a).

Submission of Signed Declaration

Applicants herein submit a Declaration under 37 C.F.R. § 1.132 signed by Dr. Yariv Siman-Tov. There is no relationship between Applicants and Dr. Siman-Tov. He was asked only to provide an opinion on the use of table salt (NaCl) as a substance for treating wounds.

This Declaration describes the effect of placing table salt in contact with the skin. When the facts in this Declaration are considered, taking into account the experimental results presented in previously-submitted Declaration describing the high concentration of salt (NaCl) used to remove tattoos, it is clear that one of ordinary skill in the art would not consider it to be obvious to use salt (NaCl) in a granular paste to be placed on a wound. In fact, based upon the scientific evidence presented in this Declaration, a skilled person would think just the opposite, *i.e.* that it would be obvious to not use salt (NaCl) in the manner that it is used by the instant inventors in their highly successful method of removing pigments.

Dr. Yariv Siman-Tov provides three references to support his opinion. Copies of these references are attached to his Declaration as Exhibits A-C.

Exhibit A: Material Safety Data Sheet (MSDS) for Sodium Chloride ACS Reagent sold by Sigma-Aldrich, February 1, 2006, 8 pages.

Exhibit B: Material Safety Data Sheet (MSDS) for RNase-Free Buffer (5M NaCl) sold by Ambion, Inc., January 10, 2006, 3 pages.

Exhibit C: Takesue, M. *Aichi Gakuin Daigaku Shigakkai Shi*. 27(1):277-316 1989. abstract only, 1 page.

If there are any formal problems with this Declaration or if additional information is required, Applicants respectfully request that the Examiner contact the undersigned to remedy the problems without unduly delaying prosecution.

Conclusion

In light of the foregoing amendments, remarks, and Declaration under 37 C.F.R. § 1.132 (including attached Exhibits A-C) this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned. No fees are believed to be due at this time. However, please charge any fee required (or credit any overpayment) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 7640-X05-045).

Respectfully submitted,

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